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EXAMINER	
WHALEY, PABLO S	
ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/828,846	BINDER ET AL.	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2010 and 19 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the Appeal Brief filed on 11/01/2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Election/Restriction

Applicant's requirement for election of species (elected were Species A (autoimmune disease that is SLE) and Species B (antigen that is Scl-70)) is hereby withdrawn after further consideration due to lack of search burden.

Status of Claims

Claims 1-33 are pending and under consideration.

Claim rejections - 35 USC § 112, 1st Paragraph

Claims 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 33 (lines 13-14) requires producing a "non-ranked" statistically derived decision. Applicant's response filed 08/19/2009, does not point to support for the newly recited limitations, and no support has been found for this limitation in the specification, drawings, or claims of the application as originally filed. As the newly recited limitations are not supported by the originally filed claims or disclosure, the claims are rejected for reciting new matter.

Claim Rejections - 35 USC § 103

Response to Arguments

Applicant's arguments filed 11/01/2010 and 08/19/2009 regarding the rejection of claims 1, 6, 10-18, and 22-33 under 35 U.S.C. 103(a) as being obvious by Zimmerman et al. (Electrophoresis, 1995, Vol. 16, p.941-947), in view of Cabello et al. (Int. J. Biomed. Comput., 1991, Vol. 27, p.77-93), and in view of Kanai (US 5,619,990; Issued: April 15, 1997) have been fully considered but are not persuasive for the following reasons.

Applicant's argue that Zimmerman, Cabello, and Kanai do not teach identifying one or more SADs wherein if the decision identifies more than one SAD, the patient sample is considered equally likely to have more than one of the identified SADs; the arguments have been fully considered. Broadly interpreted, the claims recite optional language (e.g. if the decision identifies more than one SAD) and a patient sample that is considered equally likely to have the identified SADs. A review of the specification exemplifies a k-nearest process wherein the distance values of the various points are compared, and when the values for points representing two different diseases differ by less than a minimum difference, both diseases are considered to be equally likely [0030], however these limitations are not recited in the claims. It was acknowledged that Zimmerman, Cabello, and Kanai do not specifically teach samples being equally likely to have said identified SADs. However, this limitation would have been obvious in view of the teachings of Zimmerman, Cabello, and Kanai, as discussed below. It is again noted that Kanai explicitly teaches different types of disease with the same likelihood values [Fig. 8], which meets the claim language for patient samples that are equally likely to have an identified disorder. Therefore, the examiner maintains that the combination of references teaches and/or makes obvious the claimed limitations.

Applicant's argument that Kanai teaches away from the claimed invention because Kanai does not teach an "OVERLAP CONDITION" wherein two diseases are equally likely, the argument is not persuasive. Applicant cites a passage in Kanai showing the purpose of Kanai is to identify a particular arrhythmia; in response it it noted that "the prior art's mere disclosure of more than one alternative does not

constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). See also MPEP §2123. Furthermore, as discussed above, Kanai explicitly teaches different types of disease with the same likelihood values [Fig. 8], which meets the claim language for patient samples that are equally likely to have one of multiple identified disorders. For these reasons, the examiner maintains that the combination of references teaches and/or makes obvious the claimed limitations.

The rejections of claims 2-5, 7-9, and 19-22 under 35 U.S.C. 103(a) as being obvious by Zimmerman in view of Cabello, Kanai, Osterland, and Kopecky have been withdrawn after further consideration. However, a new ground of rejection has been applied to these claims (see below).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 10-18, and 22-33 are rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman et al. (Electrophoresis, 1995, Vol. 16, p.941-947), in view of Cabello et al. (Int. J. Biomed. Comput., 1991, Vol. 27, p.77-93), and in view of Kanai (US 5,619,990; Issued: April 15, 1997).

The amended claims are drawn to a computer-implemented method of identifying whether a patient test sample is associated with one or more of a plurality of specific systemic autoimmune diseases (SADs) based on autoantibody levels present in the patient test sample; the method comprising: storing a plurality of reference data sets in a memory, each reference data set having quantitative values representing levels for each of a plurality of specific autoantibodies, wherein said reference data sets include, for each of said plurality of specific SADs, at least one reference data set for the specific SAD, and wherein said reference data sets include at least one reference data set associated with none of the specific SADs; receiving, in a computer system, a sample data set having quantitative values representing levels for each of said plurality of autoantibodies for a patient test sample; and automatically applying, in the computer system, a k-nearest neighbor process to the quantitative values of the sample data set and the reference data sets to produce a statistically derived decision indicating whether, out of a range of none, one and more than one of said systemic autoimmune diseases, the patient test sample is associated with one or more of said specific SADs,

wherein if the decision identifies more than one SAD, the patient test sample is considered equally likely to have said identified SADs; and providing the statistically derived decision as output, the decision identifying which one or more ogthe of said systemic autoimmune diseases the patient test sample is associated with if the statistically derived decision indicates that the patient test sample is associated with one or more of said systemic autoimmune diseases. Newly added claims 33 requires producing a non-ranked statistically derived decision.

Zimmerman teaches a computer-implemented method for identifying whether patient autoantibody samples are associated with autoimmune disease [Abstract]. In particular, Zimmerman teaches obtaining quantitative staining patterns from patients with autoimmune diseases and normal controls [Abstract, Section 2.1], which shows obtaining quantitative sample and reference data wherein at least one data set is associated with none of the diseases. The stained blots are scanned and stored in a database for analysis [Section 2.2, 2.3, 2.4.1, Fig. 3]. Zimmerman shows applying a multivariate discriminate analysis for comparing data of known groups to unknown samples using [p.944, Col. 2, ¶ 2], and providing a statistically derived decision as output [p.945, Col. 2 and Table 1]. Furthermore, their multivariate approach for classifying unknown samples is based on "normal" and "diseased" sample sera, wherein each is described by variables representing a particular staining behavior [p.946, Section 4]. The computer system comprises software and hardware components for implementing the above processes [Section 2.2 and 2.3]. Zimmerman shows the calculation of Chi-squared values (i.e. concordance value) and distance metric values

(d') wherein mean known vectors are compared to unknown blot patterns [p.944, Col. 2, ¶ 3]. Zimmerman shows discarding data if values exceed a certain distance value (i.e. cutoff value) [p.945, Col. 2 and Table 1]. Zimmerman shows increasing said minimal distance and recalculating the analysis [p.945, Col. 2], which is an implicit teaching for a second threshold value. The entire process is implemented on a computer system comprising hardware and software devices [Section 2.2, 2.3].

Zimmerman does not teach applying a k-nearest neighbor process to produce decisions indicating whether, out of a range of none, one or more than one of said systemic autoimmune diseases, the patient test sample is associated with none, one, and more than one of said SADs, wherein if the decision identifies more than one SAD, the patient test sample is considered equally likely to have said identified SADs, as in claims 1, 11-13, 18, 25-28, 32.

Zimmerman does not teach providing a statistically derived decision identifying which one or more of said SADs the patient sample is associated with if the decision indicates that the patient test sample is associated with one or more SADs, as in claims 1, 18, and 32.

Zimmerman does not teach producing a non-ranked statistically derived decision, as in claim 33.

Cabello teaches a k-nearest neighbor algorithm for classifying different types of heart disorders [Abstract]. In particular, the k-nearest neighbor classifiers are assigned to known and unknown data sets [Section 2, p.79-80], and distance calculations are determined [Section 3]. The k-nearest neighbor algorithm is applied to quantitative

values of sample data for classification to a plurality of different disease classes [p.83, p.87, Fig. 2]. This method is beneficial for improved data classification [p.78-79].

Kanai teaches an automated method for making statistically derived decisions that identify which specific disease the patient test sample is associated with and if there is no association [Abstract, Fig. 8, 9, 10]. In particular, Kanai teaches a generic discriminant analysis techinque for determining the degree to which a test data group is associated with multiple disease groups or a non-disease control group [Fig. 4, Fig. 7, Col. 6, lines 20-30, Col. 7, lines 30-50, Ref. Claims 20, 28, 30]. The method is based on nearest neighbor distance between test and reference data [Abstract, Col. 1, Col. 2, Fig. 4, Fig. 7(a)]. This method is beneficial for determining to which of multiple disease groups a patient belongs [Col. 1, lines 5-10].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention practicing the discriminant analysis method of Zimmerman for identifying patients with SADs to use other known types of discriminant analysis, such as k-nearest neighbor analysis, to produce decisions indicating whether, out of a range of none, one or more than one of said systemic autoimmune diseases, the patient test sample is associated with none, one, and more of said specific SADs, if the decision identifies more than one SAD, the patient test sample is considered equally likely to have said identified SADs, with a reasonable expectation of success, since Cabello teaches the classification of one or more different disorders using a k-nearest neighbor algorithm with predictable results [Section 3]. The motivation would have been to

employ other known methods of discriminant analysis that provide improved disease classification, as suggested by Cabello [p.79, ¶1].

Zimmerman, Cabello, and Kanai do not specifically teach samples being equally likely to have said identified SADs. However, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention practicing the methods of Zimmerman to identify patient samples that are "equally likely" to have more than one of the identified SADs since Zimmerman compares probability values for selecting two different SADs wherein at least one pair of them appear to be equal [Fig. 4], since Cabello displays classifier performance and shows at least two different classifiers that identify diseases with the same senstivitiy and specificity [See at least p.89, Table III], and since Kanai shows different types of disease with the same likelihood values [Fig. 8], which reasonably suggests patient samples that are equally likely. The motivation would have been to improve autoimmune disease diagnosis using a discriminant analysis technique that minimizes the possibility for misclassification and allows for the classification of complex data sets, as suggested by Cabello [p.78, last ¶, p.83, p.87, Fig. 2] and Zimmerman [Abstract].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the discriminant analysis method of Zimmerman by providing a statistically derived decision identifying which one or more of said SADs the patient sample is associated with if the decision indicates that the patient test sample is associated with one or more SADs, with a reasonable expectation of success, since Kanai k-nearest neighbor techniques for making statistically derived decisions that

identify which specific disease a patient test sample is associated with, and shows the degre of association and if there is no association, as set forth above, and since Zimmerman shows that discriminant analysis decisions for determining SAD associations are inherently statistically derived [See at least Fig. 4 and Section 4]. The motivation improve disease diagnosis using a method capable of determining if a patient is associated with multiple disease groups, as suggested by Kanai [Col. 1, lines 5-10].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the discriminant analysis method of Zimmerman to applying a k-nearest neighbor algorithm to produce a non-ranked statistically derived decision, with a reasonable expectation of success, since Kanai teaches discriminant process for making statistically derived decisions based on nearest neighbor distances between test and reference data [Abstract, Col. 1, Col. 2, Fig. 4, Fig. 7(a)], and shows predictive values that are of zero value [Fig. 8], which are interpreted as non-ranked decisions. The motivation would have been to improve diagnosis by identifying and elimating groups with no relationship to disease.

Claims 2-5, and 19-22 are rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman et al. (Electrophoresis, 1995, Vol. 16, p.941-947), in view of Cabello et al. (Int. J. Biomed. Comput., 1991, Vol. 27, p.77-93), and in view of Kanai (US 5,619,990; Issued: April 15, 1997), as applied to claims 1, 6, 10-18, and 22-32, above, and further in view of Osterland (CLINICAL CHEMISTRY, 1994, Vol. 40, No. 11(B), p.2146-2153),

Isenberg et al. (British Journal of Rheumatology, 1997, 36:229-233), and Reichlin et al. (US 5,681,700; Issued Oct. 28, 1997).

Zimmerman, Cabello, and Kanai make obvious a computer-based method for identifying patients associated with none, one, or more autoimmune diseases, as set forth above. Regarding claim 22, the computer system of Zimmerman includes hardware components for displaying data [Section 2.3].

Zimmerman, Cabello, and Kanai do not teach the use of data sets for two or more systemic autoimmune diseases (SADs) selected from the group recited in claims 2, 3, and 19.

Zimmerman, Cabello, and Kanai do not teach the use of antibodies to at least ten of the antigens recited in claims 4 and 20.

Zimmerman, Cabello, and Kanai do not teach the use of antibodies to the following antigens: SSA 60, SSA 52, SSB 48, 6 Sm, SmRNP, RNP 68, RNPA, Riboproteins P0, P 1, and P2, dsDNA, Nucleosome, Centromere B, Scl-70, and Jo-1, as in claims 5 and 21.

Osterland teaches laboratory methods for diagnosing and monitoring SADs. The method includes quantitative tests for SADs that include SLE, myositis, and MCTD [Table 4], which shows two or more SAD data sets. Reactive autoantibodies and antigens include Scl-70, Jo-1 (myositis), Sm, Sn RNP, SS-A and SS-B (which suggests SSA 60, SSA 52, and SSB 48), Centromere (which suggests centromere B), ss and

native DNA (which suggests ds DNA), Ku, Ribosomal P (which suggests riboproteins P0, P1, and P2) [page 2149, col. 1, entire, and Table 4, Table 5, p.2151, Col. 2, last ¶].

Isenberg teaches autoantibody profiles for lupus patients. In particular, Isenberg tests for antibodies to Ro/SSA, La/SSB, Sm, RNP, and Ribosomal P using ELISA [Abstract and Table 1].

Reichlin teaches a method of testing for antibodies to ds-DNA [Abstract, Table 2, and Table 3].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have modified the method made obvious by Zimmerman, Cabello, and Kanai by using data for two or more systemic autoimmune diseases (SADs) selected from the group recited in claims 2, 3, and 19, since Osterland teaches assays to test for antibodies for SADs such as SLE and MCTD, as shown above. The motivation would have been to use known methodologies to screen for known autoimmune diseases, as suggested by Osterland [page 2149, Diagnostic Tests].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have modified the method made obvious by Zimmerman, Cabello, and Kanai by using at least ten antibodies to the following antigens including SSA 60, SSA 52, SSB 48, Sm, SmRNP, RNP 68, RNPA, Riboproteins P0, P 1, and P2, dsDNA, Nucleosome, Centromere B, Scl-70, and Jo-1, since Osterland, Reichlin, and Isenberg show that autoantibodies and antigens including Scl-70, Jo-1, Sm, Sn RNP, SS-A and SS-B (which suggests SSA 60, SSA 52, and SSB 48), Centromere (which suggests centromere B), ss and native DNA (which suggests ds DNA), Ku, Ribosomal P

(which suggests riboproteins P0, P1, and P2), and ds-DNA, were known in the art and were known to be related to SADs such as SLE, as shown above. The motivation would have been to use known methodologies to screen for known autoimmune diseases, as suggested by Osterland [page 2149, Diagnostic Tests].

Osterland, Isenberg, and Reichlin do not specifically distinguish between SSA 60, SSA 52, SSB 48, SmRNP, RNP 68, RNP A, and Riboproteins P0, P1, and P2, as in claims 4, 5, 20, and 21. However, it would have been obvious for one of ordinary skill in the art at the time of the instant invention to have tested for these variations in view of the prior art of Osterland and Isenberg, who test for RNP, SSA, SSB, and Ribosomal P antibodies associated with SLE and MCTD, as shown above, and in view of the rationale for a *prima facie* case of obviousness provided by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). See MPEP 2143. In this case, the rationale would have been to test for multiple RNP, SSA, SSB, and Riboprotein antibodies based on the finite genus of known RNP, SSA, SSB, and Riboprotein proteins associated with SLE, for example.

Claims 7, 8, and 9 are rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman et al. (Electrophoresis, 1995, Vol. 16, p.941-947), in view of Cabello et al. (Int. J. Biomed. Comput., 1991, Vol. 27, p.77-93), and in view of Kanai (US 5,619,990; Issued: April 15, 1997), as applied to claims 1, 6, 10-18, and 22-32, above, and further in view of Kopecky (Design and Implementation of the Internet-Based Medical Expert System ToxoNet, 1999, p.1-153).

Zimmerman, Cabello, and Kanai make obvious a computer-based method for identifying patients associated with none, one, or more autoimmune diseases, as set forth above.

Zimmerman, Cabello, and Kanai do not teach transmitting display data to a remote computer system, as in claim 7.

Zimmerman, Cabello, and Kanai do not teach receiving reference data sets from an automated system over a network connection, as in claims 8 and 9.

Kopecky teaches an internet-based medical expert system (ToxoNet) automated classification of seriological data [p.1]. In particular, Kopecky teaches a server for storing and retrieving data from the database [Section 3.2.2], and transmitting data across a network [Fig. 3.3], and remote computing [Section 3.2.1, and Section 6.2].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to haved modified the method made obvious by Zimmerman, Cabello, and Kanai, by transmitting display data to a remote computer system, and receiving reference data sets from an automated system over a network connection, with a reasonable expectation of success, since internet-based server devices for storing and transmitting data from a database would have been known to one skilled in the art, as taught by Kopecky, above, and since one skill in the art would have been able to use these devices for transmitting data across networks with predictable results, as taught by Kopecky [Fig. 3.3, Section 3.2.1, and Section 6.2]. The motivation would have been to improve disease diagnosis by providing remote automated decision support to clinicians, as suggested by Kopeck [Section 3.2.1, and 6.2].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 11am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

Art Unit 1631

/PW/

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631